DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

October 31, 2001

WARNING LETTER NO. 2002-NOL-07

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Janice T. Stewart, President
Stewarts Seafood Inc. d.b.a.
Captain Jim's Seafood
8401 Highway 188
Coden, Alabama 36523

Dear Mrs. Stewart:

We inspected your firm, located at 8401 Highway 188, Coden, Alabama, during September 18-21, 2001, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations, some of which were previously brought to your attention, cause your cooked, ready-to-eat crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit of minimum time, temperature, and pressure for cooked crabmeat at the "Cooking" critical control point to control pathogen growth and toxin formation. Your firm has no records documenting the calibration of the retort temperature and pressure gauges, including gauges used during your thermal penetration study dated May 3, 2000.

- You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen growth and toxin formation when your process for cooked crabmeat deviated from your critical limit at the "Cooking" critical control point. Your thermal penetration study, dated May 3,

2000, specifies 800-pound cook loads. Our investigator documented cook loads averaging 880 pounds on September 18, 2001, and 917 pounds on September 19, 2001.

In addition, your firm did not take adequate corrective action to control pathogen growth and toxin formation when the temperature of cooked crabmeat deviated from the critical limit of picked crabmeat temperature at or below 50°F at all times at the "Picking and Packing" critical control point. On September 19, 2001, our investigator documented temperatures of containers of cooked crabmeat during the picking operations ranging from 50°F to 56°F.

- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Cooking" critical control point to control pathogen growth and toxin formation listed in your HACCP plan for cooked crabmeat. On September 19, 2001, our investigator documented that actual cook times were not being recorded as required by your HACCP plan.

In addition, the investigator documented numerous insanitary conditions that cause the cooked crabmeat you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations were as follows:

- Picking employees were observed using knives with etchings in the handles to pick crabmeat. A black residue was observed on several of these knives. The picking employees routinely contacted the knife handles and then contacted cooked crabmeat without washing or sanitizing their hands before handling the cooked crabs.

- Employees were routinely observed contacting insanitary objects and then contacting cooked crabmeat without washing and sanitizing their hands before handling the cooked crabs.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as verification data, calibration records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

Richard D. Debo
Acting District Director
New Orleans District

Enclosure: FDA Form 483